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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,971	06/09/2005	Yoshihiro Ohmiya	2008_0957	8735
513 7590 11/05/2009 WENDEROTH, LIND & PONACK, L.L.P. 1030 15th Street, N.W., Suite 400 East Washington, DC 20005-1503				
EXAMINER				
NOAKES, SUZANNE MARIE				
ART UNIT		PAPER NUMBER		
1656				
MAIL DATE		DELIVERY MODE		
11/05/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/537,971

Applicant(s)

OHMIYA ET AL.

Examiner

SUZANNE M. NOAKES

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16, 17 and 22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16, 17 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of the Application

1. The amendments and remarks filed 10 August 2009 are acknowledged.
Applicants have amended claim 16 and cancelled claims 23-25. Claims 16, 17 and 22 are pending and subject to Examination on the merits.

Withdrawal of Rejections/Objections

2. Any rejection/objection recited in the previous Office action and not explicitly restated below is hereby withdrawn.
3. The rejection of claims 16, 17 and 22-25 under 35 USC 112 1st paragraph – written description, New Matter, is withdrawn in view of the amendments to claim 16 which recites that the method utilizes SEQ ID NO: 2, which was originally disclosed in the original claims and specification.
4. The objection to the specification for introducing new matter is hereby withdrawn upon further consideration and upon Applicants Declaration and Remarks stating that all instances of the species *Cypridina noctiluca* was an error and should have recited *Vargula hilgendorfi*. It is noted that SEQ ID NO: 2 was originally filed in the claims and the specification; Applicants assert that the use of the wrong organism was merely a typographical mistake at the time of filing (see Declaration filed 02/27/2009, Remarks from the same date). It is noted that *V. hilgendorfi* is well known to contain this particular luciferase which is part of the monitor protein (a fusion protein of luciferase, cleavage site and yellow fluorescent protein) and thus one skilled in the art would be

able to isolate and use the noted luciferase (which was first isolated in 1989) to make use the instant invention. On the other hand, a luciferase from *Cypridinia noctiluca* was not isolated until post-filing, albeit it was Applicants own work. However, all abbreviations in the specification referring to the *V. hilgendorfi* are to "Vluc" and not to "Cluc" thus also suggesting that the argument of a typographical error to be accurate. Thus, based on Applicants arguments and the assessment that SEQ ID NO: 2 was originally filed in the specification and the claims and thus fully disclosed and supported, changing the occurrences of *Cypridinia noctiluca* to *V. hilgendorfi* now fully supports the claimed invention, e.g. use of SEQ ID NO: 2. Thus, the objection to the specification is withdrawn.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

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1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 16, 17 and 22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 9-12 and 18 of U.S. Patent No. 7,544,484. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 9 of the '569 application is drawn to an isolated polynucleotide comprising SEQ ID NO: 1 which encodes a chimeric monitor protein of the following form: a *Vargula* luciferase and yellow fluorescent protein (YFP) which according to Figure 1b, also encodes for a linker peptide between the luciferase and YFP – said polynucleotide notably encodes for a protein which is 100% identical to the instant SEQ ID NO: 2 (see alignment below and results in SCORE). The other claims of the '569 application are drawn to vectors, transformants and methods of making said chimeric fusion proteins. As such, it would be obvious to use the noted DNA and

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encoded protein in the instant claimed methods for using such a chimeric fusion protein to quantitatively monitor the energy change in energy transfer between the YFP and luciferase.

RESULT 1
ADL56773
ID ADL56773 standard; DNA; 2502 BP.
XX
AC ADL56773;
XX
DT 03-JUN-2004 (first entry)
XX
DE DNA encoding chimeric protein #2.
XX
KW ds; gene; secretory chimeric protein; membrane-bound chimeric protein;
KW antidiabetic; antiinflammatory.
XX
OS Unidentified.
XX
FH Key Location/Qualifiers
FT CDS 1. .2502
FT /*tag= a
FT /product= "Chimeric peptide #2"
XX
PN WO2004022600-A1.
XX
PD 18-MAR-2004.
XX
PF 04-SEP-2003; 2003WO-JP011285.
XX
PR 06-SEP-2002; 2002JP-00261229.
PR 10-DEC-2002; 2002JP-00357407.
XX
PA (NAAD-) NAT INST ADVANCED IND SCI & TECHNOLOGY.
XX
FI Ohmiya Y, Ashitaka E, Ito S;
XX
DR WPI; 2004-248450/23.
DR P-PSDB; ADL56783.
XX
PT Chimeric secretory or membrane-bound protein containing an energy
PT generating protein and an energy accepting protein for use as a reporter
PT of gene expression.
XX
PS Disclosure; SEQ ID NO 2; 57pp; Japanese.
XX
CC The invention relates to secretory or membrane-bound chimeric proteins,
CC containing an energy generating protein bound to an energy accepting

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CC protein, in which energy transfer between the generating and accepting
 CC proteins can take place. The proteins are useful as a reporter for gene
 CC expression within the cell, for example to monitor the effect within the
 CC cell of antidiabetic or antiinflammatory drugs. The present sequence
 CC represents DNA encoding a chimeric protein of the invention
 XX
 SQ Sequence 2502 BP; 712 A; 609 C; 647 G; 534 T; 0 U; 0 Other;

Alignment Scores:

Pred. No.:	0	Length:	2502
Score:	4504.00	Matches:	833
Percent Similarity:	100.0%	Conservative:	0
Best Local Similarity:	100.0%	Mismatches:	0
Query Match:	100.0%	Indels:	0
DB:	12	Gaps:	0

US-10-537-971-2 (1-833) x ADL56773 (1-2502)

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Qy      1 MetLysIleIleIleLeuSerValIleLeuAlaTyrCysValThrAspAsnCysGlnAsp 20
      |||
Db      1 ATGAAGATAATAATTCGTCTGTATATTGGCCTACTGTGTACCGCAACACTGCTCAAGAT 60

Qy     21 AlaCysProValGluAlaGluProProSerSerThrProThrValProThrSerCysGlu 40
      |||
Db     61 GCATGTCCTGTAGAAGCGGAAACCGCCATCAAGTACACCAACAGTTCCAACTTCTGTGAA 120

Qy     41 AlaLysGluGlyGluCysIleAspThrArgCysAlaThrCysLysArgAspIleLeuSer 60
      |||
Db    121 GCTAAGAAGAGAGAAATGTATAGATACCAGATGCGCAACATGTAAACGAGATATACTATCA 180

Qy     61 AspGlyLeuCysGluAsnLysProGlyLysThrCysCysArgMetCysGlnTyrValIle 80
      |||
Db    181 GATGACTGTGTGAAAATAAACAGGGAAGACATGCTGTAGAAATGTGCGAGTATGTGATT 240

Qy     81 GluCysArgValGluAlaAlaGlyTyrPheArgThrPheTyrGlyLysArgPheAsnPhe 100
      |||
Db    241 GAATGCAGAGTAGAAGCAGCTGTTATTTAGAACGTTTACGGCAAAAGATTAAATTT 300

Qy    101 GlnGluProGlyLysTyrValLeuAlaArgGlyThrLysGlyGlyAspTrpSerValThr 120
      |||
Db    301 CAGGAACCTGTAATATGTGCTGCTGACGAGGGAACCAAGGGTGCGGATTTGGCTGTATACC 360

Qy    121 LeuThrMetGluAsnLeuAspGlyGlnLysGlyAlaValLeuThrLysThrThrLeuGlu 140
      |||
Db    361 CTCACCATGGAGAATCTAGATGGACAGAAAGGAGCTGTGCTGACTAAGACCAACTGGAG 420

Qy    141 ValAlaGlyAspValIleAspIleThrGlnAlaThrAlaAspProIleThrValAsnGly 160
      |||
Db    421 GTTGAGGAGAGAGCTAATAGACATTACTCAAGCTACTGAGAGTCTTATCACAGTTAAGCGGA 480

Qy    161 GlyAlaAspProValIleAlaAsnProPheThrIleGlyGluValThrIleAlaValVal 180
      |||
Db    481 GGAGCTGACCCAGTTATGCTAACCCGTTTCACAAITGGTGGGTGACCATTTGCTGTGTGTT 540

Qy    181 GluIleProGlyPheAsnIleThrValIleGluPhePheLysLeuIleValIleAspIle 200
      |||
Db    541 GAAATACCGGGCTCAATATCACAGTCAATGCAATTCITTAACATAATGCTGATTGATATT 600

Qy    201 LeuGlyGlyArgSerValArgIleAlaProAspThrAlaAsnLysGlyLeuIleSerGly 220
      |||
Db    601 CTGGAGAGAGATCTGTGAGAAATTGCTCCAGACACAGCAAAACAAGGACTGATATCTGGT 660

Qy    221 IleCysGlyAsnLeuGluMetAsnAspAlaAspAspPheThrThrAspAlaAspGlnLeu 240

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|||||
Db 661 ATCTGTGGTAATCTGGAGATGAATGACGCTGATGACTTACTACAGATGCAGATCAGCTG 720
Qy 241 AlaIleGlnProAsnIleAsnLysGluPheAspGlyCysProPheTyrGlyAsnProSer 260
Db 721 GCGATCCAAACCAACATAAACAAGAGTTCGACGGCTGCCCATTTCTATGGCAATCCTTCT 780
Qy 261 AspIleGluTyrCysLysGlyLeuMetGluProTyrArgAlaValCysArgAsnAsnIle 280
Db 781 GATATCGAATACTGCAAGGTCTGATGGAGCCATACAGAGCTGTATGTGCTAAACATATC 840
Qy 281 AsnPheTyrTyrTyrThrLeuSerCysAlaPheAlaTyrCysMetGlyGlyGluGluArg 300
Db 841 AACTTCTACTATTACACTCTATCCTGTGCCTTCGCTTACTGTATGGAGGAGAGAAAGA 900
Qy 301 AlaLysHisValLeuPheAspTyrValGluThrCysAlaAlaProGluThrArgGlyThr 320
Db 901 GCTAAACACGTCCTTTTCGACTATGTTGAGACATGCGCTGCGCGGAAACGAGAGGAACG 960
Qy 321 CysValLeuSerGlyHisThrPheTyrAspThrPheAspLysAlaArgTyrGlnPheGln 340
Db 961 TGTGTTTTATCAGGACATACCTTCTATGACACATTGCAAAAGCAAGATATCAATCCAG 1020
Qy 341 GlyProCysLysGluIleLeuMetAlaAlaAspCysTyrTrpAsnThrTrpAspValLys 360
Db 1021 GSCCATGCAAGGAGATTCTGATGSCCGCAGACTGTTACTGGAACACATGGGATGTAAG 1080
Qy 361 ValSerHisArgAspValGluSerTyrThrGluValGluLysValThrIleArgLysGln 380
Db 1081 GTTTCACATAGAGAGCTCGAATCATACACTGAGGTAGAGAAAGTAAACAATCAGAAACAG 1140
Qy 381 SerThrValValAspLeuIleValAspGlyLysGlnValLysValGlyGlyValAspVal 400
Db 1141 TCAACTGTAGTAGATCTCATTTGTGGATGGCAAGCAGCTCAAGGTTGGAGGAGTGGATGTA 1200
Qy 401 SerIleProTyrSerSerGluAsnThrSerIleTyrTrpGlnAspGlyAspIleLeuThr 420
Db 1201 TCTATCCCGTACAGCTCTGAGAACACTTCCATATACTGGCAGGATGGAGACATCCTGAGC 1260
Qy 421 ThrAlaIleLeuProGluAlaLeuValValLysPheAsnPheLysGlnLeuLeuValVal 440
Db 1261 ACGGCATCCTACCTGAAGCTCTTGTGCTTAAGTTCACCTTAAGCAGCTCCTGTAGTT 1320
Qy 441 HisIleArgAspProPheAspGlyLysThrCysGlyIleCysGlyAsnTyrAsnGlnAsp 460
Db 1321 CATATCAGAGATCCATTGATGGAAGACATSCGCATATGTGTTAACTATAATCAAGAT 1380
Qy 461 SerThrAspAspPhePheAspAlaGluGlyAlaCysAlaLeuThrProAsnProProGly 480
Db 1381 TCAACTGATGATTTCTTTGACGCGAAGGAGCATGCGCTCTAAACCCCAACCCCAAGGA 1440
Qy 481 CysThrGluGlnLysProGluAlaGluArgLeuCysAsnAsnLeuPheAspSerSer 500
Db 1441 TGTACAGAGGAACAGAAACAGAGCTGAGCGACTTTGCAATAATCTCTTTGATCTCTCT 1500
Qy 501 IleAspGluLysCysAsnValCysTyrLysProAspArgIleAlaArgCysMetTyrGlu 520
Db 1501 ATCGACGAGAAATGTAAATGCTGCTACAAAGCTGACCGGATTGCCGATGTATGTACGAG 1560
Qy 521 TyrCysLeuArgGlyGlnGlnGlyPheCysAspHisAlaTrpGluPheLysLysGluCys 540
Db 1561 TATTGTGCTGAGGGGCAACAAAGGATTTTGTGACCATGCTTGGGAGTTCAAGAAAGAAATGC 1620
Qy 541 TyrIleLysHisGlyAspThrLeuGluValProProGluCysGlnGlySerThrGluPro 560
Db 1621 TACATAAAACATGGAGACACTCTAGAAGTACCACCTGAATGTCAAGGATCCACAGAGGCC 1680

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Qy 561 GlyLeuGluGluValGlyGluIleGluGlnLysGlnLeuGlnLysArgPheGlyGlyPhe 580
 Db 1681 GGCCTGAGAGAGGTGGGGAGATTGAGCAGAAACAGTCAGAAAGCGGTTCGGGGGCTTC 1740

Qy 581 ThrGlyAlaArgLysSerAlaArgLysLeuAlaAsnGlnGlySerValSerLysGlyGlu 600
 Db 1741 ACCGGGCCCCGAAGTCGGCCCCGAAGTTGGCCAAACAGGATCGTGAGCAAGGGCAG 1800

Qy 601 GluLeuPheThrGlyValValProIleLeuValGluLeuAspGlyAspValAsnGlyHis 620
 Db 1801 GAGCTGTTCCACCGGGGTGGTCCCATCCTGTGAGCTGGACGGCAGCTAAACGGCCAC 1860

Qy 621 LysPheSerValSerGlyGluGlyGluGlyAspAlaThrTyrGlyLysLeuThrLeuLys 640
 Db 1861 AAGTTCACGCTGTCCGCGCAGGGCCAGGGCGATGCCACCTACGGCAAGCTACCCCTGAAG 1920

Qy 641 PheIleCysThrThrThrGlyLysLeuProValProTrrProThrLeuValThrThrPheGly 660
 Db 1921 TTCATCTGCACACCGGCAAGCTGCGCGTGCCTGGCCACCTCGTGACCACTTCGGC 1980

Qy 661 TyrGlyLeuGlnCysPheAlaArgTyrProAspHisMetLysGlnHisAspPheLys 680
 Db 1981 TACGGCCTGCAGTGTCTTCGCCGCTACCCCGACCACATGAAGCAGCAGCACTTCTTCAAG 2040

Qy 681 SerAlaMetProGluGlyTyrValGlnGluArgThrIlePhePheLysAspAspGlyAsn 700
 Db 2041 TCCGCCATGCCCGAAGGCTACGTCCAGGAGCGCACCATCTTCTTCAAGGACGACGGCAAC 2100

Qy 701 TyrLysThrArgAlaGluValLysPheGluGlyAspThrLeuValAsnArgIleGluLeu 720
 Db 2101 TACAAGACCCGCGCCGAGGTGAAGTTCGAGGSCGACACGCTGGTGAACCGCATCGAGCTG 2160

Qy 721 LysGlyIleAspPheLysGluAspGlyAsnIleLeuGlyHisLysLeuGluTyrAsnTyr 740
 Db 2161 AAGGCAATCGACTTCAAGGAGGACGGCAACATCCTGGGGCACAGCTGGAGTACAACTAC 2220

Qy 741 AsnSerHisAsnValTyrIleMetAlaAspLysGlnLysAsnGlyIleLysValAsnPhe 760
 Db 2221 AACAGCCACAACGTCTATATCATGCGCGACAGCAGAAGAACGGCATCAAGGTGAACCTTC 2280

Qy 761 LysIleArgHisAsnIleGluAspGlySerValGlnLeuAlaAspHisTyrGlnGlnAsn 780
 Db 2281 AAGATCCGGCACAAATCGAGGACGGCAGCGTGCAGCTGCGCGACCACTACCAGCAGAAAC 2340

Qy 781 ThrProIleGlyAspGlyProValLeuLeuProAspAsnHisTyrLeuSerTyrGlnSer 800
 Db 2341 ACCCCCATCGCGCAGCGCCCCGTGCTGCTGCCCGACACCACTACTCTGAGTACCAGTCC 2400

Qy 801 AlaLeuSerLysAspProAsnGluLysArgAspHisMetValLeuLeuGluPheValThr 820
 Db 2401 GGCCTGAGCAAGAGACCCCAACGAGAAGCGGATCACATGGTCTGCTGGAGTTCGTGACC 2460

Qy 821 AlaAlaGlyIleThrLeuGlyMetAspGluLeuTyrLys 833
 Db 2461 GCCCGCGGATCACTCTCGGCATGGACGAGCTGTACAAG 2499

Response to Arguments

7. Applicants arguments filed 10 August 2009 have been fully considered. The remarks and amendments to the claims on the one hand are convincing to necessitate the withdrawal of all previous New Matter rejections and objections as outlined above. However, upon further consideration and comparison the issued US Patent 7,544,484 and the instant claims, the Obvious Double Patenting rejection is made (and also made non-provisional).

Conclusion

8. No claim is allowed.
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUZANNE M. NOAKES whose telephone number is (571)272-2924. The examiner can normally be reached on 7.00 AM-3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SUZANNE M. NOAKES/
Primary Examiner, Art Unit 1656
03 November 2009